FEHLING FALK sternal retractor

Retractor body	MQI-1	FALK sternal retractor, interchangeable blades, body only

Components

FALK retractor blades

MQI-2	Retractor blade 34 x 100 mm (pair)
MQI-3	Retractor blade 43 x 100 mm (pair)

Atrial retractor

MRV-4V	HOHE atrial retractor fixed 30 x 20 x 150 mm
MRV-4H	HOHE atrial retractor fixed 65 x 20 x 150 mm
MRV-3H	HOHE atrial retractor fixed 65 x 30 x 150 mm
MRV-2H	HOHE atrial retractor fixed 45 x 45 x 150 mm
MRV-4L	HOHE atrial retractor fixed 65 x 20 x 200 mm
MRV-3L	HOHE atrial retractor fixed 65 x 30 x 200 mm
MPF-1H	HOHE atrial retractor fixed 65 x 40 x 200 mm
MRV-2H	HOHE atrial retractor tricuspid fixed 45 x 45 x 150 mm
MRV-2L	HOHE atrial retractor tricuspid fixed 45 x 45 x 200 mm
MQG-1	Aortic punch small 20 mm with ball connector Ø 7 mm
MQG-2	Aortic punch medium 30 mm with ball connector Ø 7 mm
MQG-3	Aortic punch large 40 mm with ball connector Ø 7 mm

Other retracting elements

MNU-1V	Flexible holding device, universal for sternal/thoracic retractors
MRR-3V	Myocardial stabilizer with ball connector Ø 7 mm
MQG-5	Zenker hook with ball connector Ø 7 mm

Clamping elements

MZZ-1Q	Clamping element for length and height adjustable ball adapter, flat
MZZ-1N	Clamping element for length and height adjustable ball adapter, small clamping range
MZZ-2	Clamping element for length and height adjustable ball adapter, with crank

Ball adapter

MRV-0F	Ball adapter bayonet Ø 6.35 mm, adjustable length and height
MRV-0J	Ball adapter bayonet with joint Ø 6.35 mm, adjustable length and height
MRV-0R	Ball adapter bayonet with joint Ø 6.35 mm, adjustable length and height

Accessories

LMT-4	Cardan screwdriver

This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.

The FALK sternal retractor may only be used, reprocessed and disposed of by qualified medical personnel!

The FALK sternal retractor is intended for reuse.

1) Intended purpose

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The FALK sternal retractor is intended for short-term application.

Field of application: Retracting and guiding instruments are used in all patients where products and tissues must be held or fixed in or at a specific position and/or moved into or at a specific position.

User profile: Retracting and guiding instruments may only be used by medically trained personnel (e.g., a medical specialist).

Application environment: Retracting and guiding instruments are only used under controlled environmental conditions (e.g., an operating room).

2) Indications

Treatment methods which require retracting and guiding of products and tissues.

3) Contraindication

All applications which run contrary to the physical and/or mechanical properties of the individual retracting and guiding instrument models are contraindicated. There are no generally applicable contraindications for the use of retracting and guiding instruments.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects

The medical literature describes the following side effects, which may also possibly occur during the intended use of the FALK sternal retractor:

- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses
- Ischemia of other organs due to compression of blood vessels

⚠	Medical devices may, for example, contain PEEK, chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
The FEHLING INSTRUMENTS FALK sternal retractor is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before any further use (see 6) Reprocessing).	
⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	Handle the FALK sternal retractor with care during storage, transport and cleaning! Avoid striking and applying pressure to the FALK sternal retractor, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.
⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Do not clean instruments containing plastic components with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.
Limitations on reprocessing	Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").
General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning.

	Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.
Initial treatment at the place of use	Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40 °C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with water (potable water quality, <40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution.

	• If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, <40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2 % Neodisher® MediClean forte in water (potable water quality) at 55 °C • Emptying • Rinse for 2 minutes with water (potable water quality, <40 °C) • Emptying • Rinse for 1 minute with cold deionized water (<30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.

Cleaning: Manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, <40 °C) with a suitable disinfectant solution (e.g. 0.5 % Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.

Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly
Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert

	Procedure/Parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.	
	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

The MQI-1 retractor body, together with its components, forms the FALK sternal retractor.

This is a U-shaped bar retractor with one fixed and one movable retractor arm. The movable retractor arm is moved along the toothed rack via a gear drive using the drive lever and pinion. The blades are attached to the distal end of the retractor arms.

The Falk sternal retractor is intended specifically for exposure of the thorax in total and partial sternotomy accesses for further surgically invasive treatment of the heart.

Figure 1 gives a configuration example for the FALK sternal retractor with an atrial retractor attached to a ball adapter and a clamping element. Table 1 lists the corresponding components.

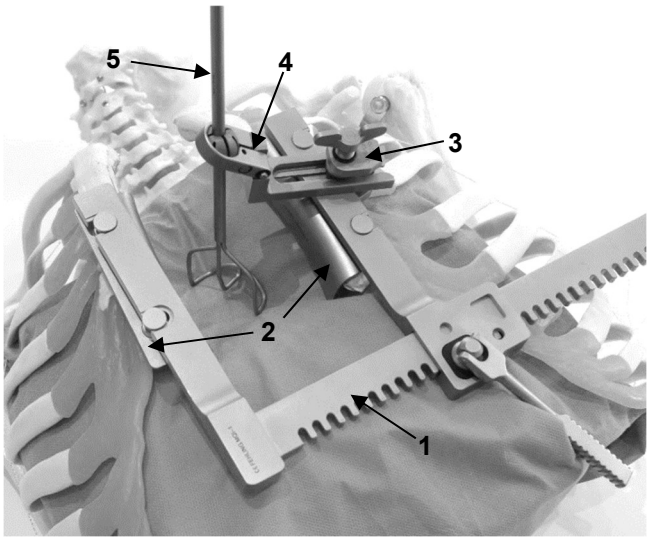


Fig. 1: Configuration example for a FALK sternal retractor with an atrial retractor attached to a ball adapter with clamping element.

Table 1: List of the corresponding components

	Article no.	Description
1	MQI-1	FALK sternal retractor, body only
2	MQI-2	Retractor blades 34 x 100 mm
3	MZZ-1Q	Clamping element
4	MRV-0J	Ball adapter bayonet with joint Ø 6.35 mm, adjustable length and height
5	MRV-2H	HOHE atrial retractor tricuspid fixed 45 x 45 x 200 mm

⚠	Use only sterilized products of sound quality!
⚠	Before employing the FALK sternal retractor, ensure that the surgical field is prepared accordingly.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.

During use

Depending on the purpose of surgery and the available space for assembly, the blades can be connected to the retractor body either before (Fig. 2) or after (Fig. 3) insertion into the sternal saw gap.

1	By inserting the cylindrical pins into the two drill holes of the retractor arms, the blades are first connected to the retractor body and then inserted into the saw cut (Fig. 2).

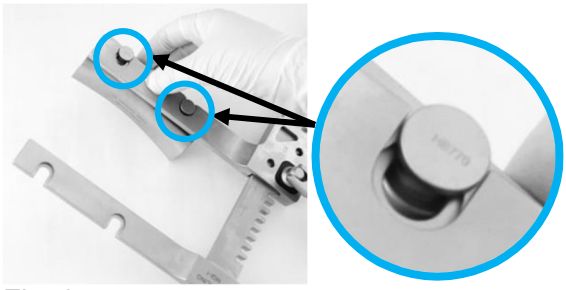
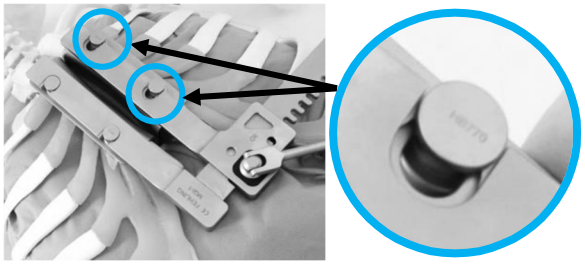
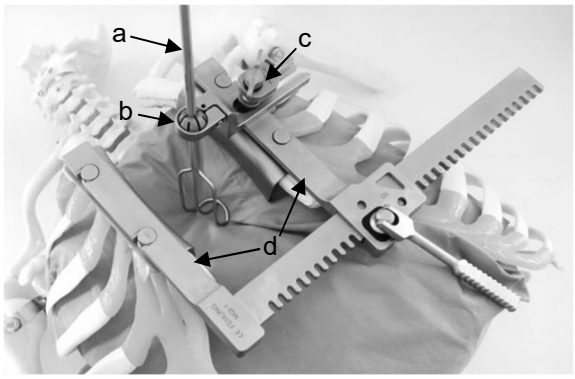


Fig. 2

2	The blades are first inserted into the saw cut. Then insert the two arms into the space between the blade pins one after the other and slide the respective holes of the arms over the blade pins. This can be performed with the retractor body either closed or slightly open (fig. 3).	 Fig. 3
3	For exposure of the thorax, open the retractor as far as necessary using the gear control (Fig. 4). For positioning the atrial retractor (a), e.g. MRV-3H, ball adapters (b) (see Components) can be attached to the retractor arms (d) in any position - also in the area of the blades - using the MZZ-1Q clamping element (c). Assembly is according to the G217 Instructions for Use.	 Fig. 4
⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.	

8) Required accessories

No accessories are necessary for using the FALK sternal retractor.

A cardan screw driver (Fig. 5) is required for application of the MRV-0F ball adapter.

Fig. 5: Cardan screw driver LMT-4

9) Assembly

For assembly and disassembly of the flexible holding device (MNU-1V), please refer to the M27 assembly instructions.

For assembly of the FALK sternal retractor, please observe the following assembly instructions.

To assemble the retractor blades, please observe 7) Configuration and Application - during application.

Figure 6 illustrates the FALK sternal retractor, which is a U-shaped bar retractor with pinion. The bar retractor consists of one fixed retractor arm (1), a toothed rack (2) and one movable retractor arm (4).

The proximal end of the movable retractor arm is the cage (5) in which the drive lever (3) is located.

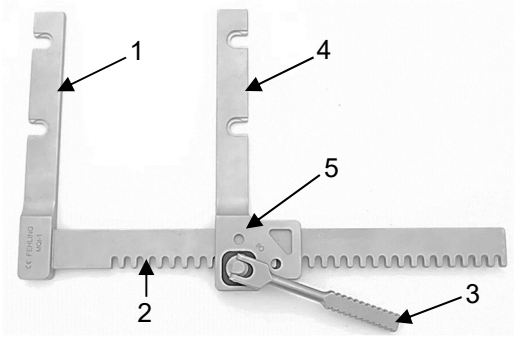


Fig. 6

First insert the drive lever (3) into the recess provided for this purpose in the cage (5) (Fig. 7).

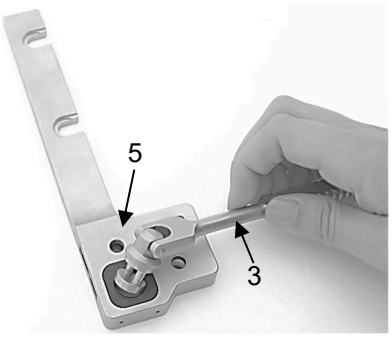


Fig. 7

Insert the toothed rack (2) into the recess of the cage (5) until the pinion of the drive lever (3) engages in the toothed rack (2) (Fig. 8).

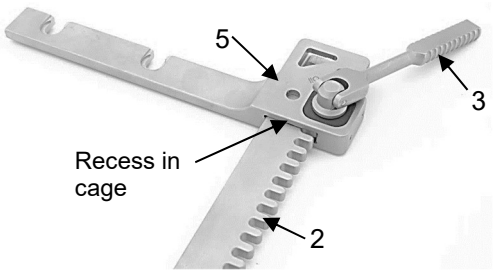


Fig. 8

⚠ Ensure that both retractor arms point in the same direction as shown in Figure 9.

By rotating the drive lever (3) clockwise, transport the movable retractor arm (4) on the toothed rack (2) inwards towards the fixed retractor arm (1) (Fig. 9).

Following a functional test, the assembled instrument is now ready for use again.

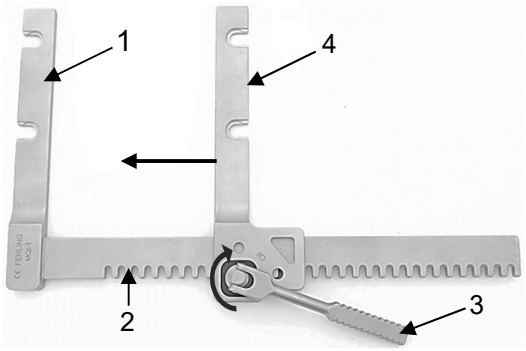


Fig. 9

10) Disassembly

The FALK sternal retractor must be disassembled as follows for reprocessing.

To disassemble the retractor blades, please observe 7) Configuration and Application - during application.

By rotating the drive lever (3) counterclockwise, transport the movable retractor arm (4) on the toothed rack (2) outwards until it can be removed.

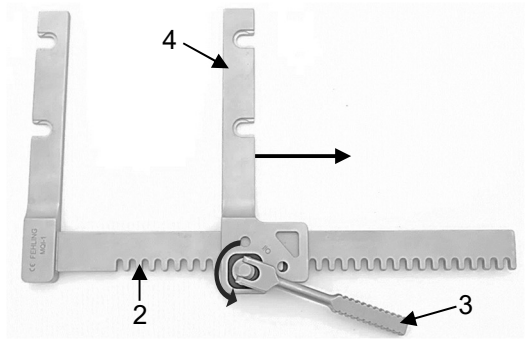


Fig. 10

In a second step, remove the drive lever (3).

The instrument is now disassembled into three separate parts (Fig. 11) and can be reprocessed.

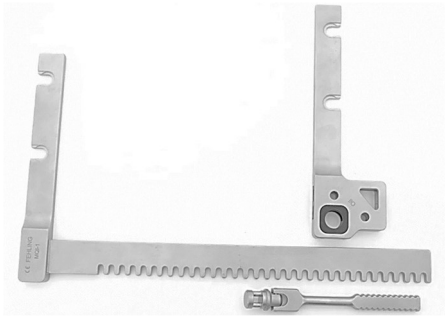


Fig. 11

⚠	Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning and reprocessing!

11) Obligation to report serious incidents

The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols

In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:

Manufacturer	Instructions for Use are to be observed	Warning
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated

To contact the manufacturer:	
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